

SUPPORT FOR THE AMENDMENTS

Claims 3, 4, 11-13, 15, 27-29, and 33-58 were previously canceled.

Claim 1 is amended.

The amendment to Claim 1 is supported by original Claims 1 and 15. Additional support for the amendment to Claim 1 is provided by the specification as originally filed, for example, at Example 2.

No new matter has been added by the present amendments.

REMARKS

Claims 1, 2, 5-10, 14, 16-26, and 30-32 are pending in the present application.

The rejection of Claims 1, 2, 5-10, 14, 16-23, and 30-32 under 35 U.S.C. §103(a) over Walker (Pediatrics in Review, 1981) in view of Kobayashi (JP 58088323), is respectfully traversed.

In the Office Action the Examiner has now cited Walker in combination with Kobayashi. Walker simply discloses that chronic nonspecific diarrhea of infancy (CNSD) or irritable bowel syndrome are a common GI problem confronted by pediatricians. Walker does not disclose any treatment program, especially one using a pharmaceutical composition comprising lysine and arginine, wherein the lysine is in a salt form with glutamic acid. Kobayashi is cited as allegedly disclosing the administration of the claimed composition for treating infantile diarrhea and dyspepsia. However, Kobayashi fails to disclose treatment of irritable bowel syndrome. Accordingly, Walker and Kobayashi simply disclose infantile GI diseases; however, there is no disclosure that irritable bowel syndrome is stress-induced disease.

Again relying upon generic excerpt from *KSR International Co. v. Teleflex Inc.*, the Examiner alleges that, despite the individual deficiencies in Walker and Kobayashi, the artisan would have found it obvious to treat irritable bowel syndrome with the claimed composition. However, peeling back the naked allegations of the Examiner it is clear that the Examiner's combination of references is nothing more than an assertion that the claimed invention would have been in the general capabilities of the skilled artisan. Indeed, there is nothing in either of Walker or Kobayashi that suggest the invention as claimed and the artisan would have only arrived at the same by reference to Applicant's disclosure.

As Applicants have reminded the Examiner on a number of occasions, at best, the modifications in the cited references to arrive at the specifically claimed combination of components and treatment method amount to nothing more than an “invitation to experiment” or “obvious to try”; however, “obvious to try” has long been held *not* to constitute obviousness. *In re O'Farrell*, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988). A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. *In re Deuel*, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995).

*KSR International Co. v. Teleflex Inc.*, 550 U.S.\_\_\_\_, 82 USPQ2d 1385 (2007) does not eliminate the “obvious to try is not obvious” standard, as it clearly states that “obvious to try” may constitute obviousness, but only under certain circumstances. Specifically, *KSR* stated that the fact that a claimed combination of elements was “obvious to try” might show that such combination was obvious under 35 U.S.C. § 103, since, if there is design need or market pressure to solve problem, and there are finite number of identified, predictable solutions, person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. However, the Examiner offers nothing more than blanket assertions and fails to show how these factors apply and whether there would be such an expectation or anticipated success.

In the present invention, irritable bowel syndrome is one of the enumerated diseases induced by stresses under current complex social environment. In such a current complex social environment, it is confirmed that the incidence of stress-induced diseases is high because sensitivity to stresses and the like from outer environment is increased. And, it seems natural that the subject (patient) of irritable bowel syndrome will receive such severe stresses. Also, in the Description, it is described that stress-induced diseases mean organ

disorders of brain (mind) *per se* or peripheral organs via the affection of the autonomic nervous system or the endocrine system with psychological or physical stressful stimulants (stressors) directly or via the brain emotional system (see page 3, lines 4-7).

Accordingly, there is a clear distinction between the present invention and cited documents (Walker and Kobayashi). That is, the stress-induced irritable bowel syndrome defined in the present invention has nothing to do with infantile GI diseases disclosed in cited documents. There is no disclosure or suggestion that the treatment of infantile GI diseases leads the treatment of subjects suffering from irritable bowel syndrome induced by stresses under current complex social environment. Especially, according to Walker, it is recognized that irritable bowel syndrome disclosed therein is merely specific for infants. Thus, it is not reasonable that the treatment for subjects suffering from stress-induced irritable bowel syndrome can be led by the treatment of infantile GI diseases.

Moreover, Applicants submit that the claimed invention would not be obvious in view of the combined disclosures of Walker and Kobayashi for yet another reason – anachronism. Specifically, Applicants submit that anachronism exists between the present invention and cited references (Walker and Kobayashi). Actually, Walker was published in 1981 and Kobayashi was published in 1983; on the other hand, the present application was filed in 2003. There is almost 20 years difference between the time of filing the present application and the time of publishing cited documents. Considering social background differences between them, it is natural that social stresses at the time of filing the present application were more severe than that at the time of publishing cited documents. Accordingly, it is believed that especially psychological stress induced by complex social environment had been changed more complex.

Further, Walker and Kobayashi merely disclose infantile GI diseases and not disclose that irritable bowel syndrome is stress-induced disease. Thus, needless to say, it is impossible that the treatment for subjects suffering from irritable bowel syndrome caused by such a current complex social environment at the time of filing the present application can be led by the treatment of infantile GI diseases in the early 1980s.

Thus, it is not reasonable that the treatment of subjects suffering from irritable bowel syndrome induced by severe psychological stress under current complex social environment is based on merely the infantile GI diseases in a different social environment era. In view of the foregoing, Applicants submit that such a method would not be obvious.

Withdrawal of this ground of rejection is requested.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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